UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

Subject: EPA Reg. No.: 802-591

From: Mark J. Perry, Biologist
Precautionary Review Section
Registration Support Branch
Registration Division (7505W)

MJP 9-27-94

To: Joanne I. Miller, PM 23/ Dan Kenny
Fungicide-Herbicide Branch
Registration Division (7505C)

Applicant: The Chas. H. Lilly Co.
7737 NE Killingsworth
Portland, OR 97218

FORMULATION FROM LABEL:

	% by wt.
Active Ingredient(s): Zinc as metallic	99.0
Inert Ingredient(s):	1.0
Total:	100%

BACKGROUND

The Chas. H. Lilly Co. submitted a rebuttal to a dermal sensitization study reviewed by PRS (J. Hayes, 2/9/94) in connection with the zinc salts RED. The registrant claims that additional dermal sensitization testing is not necessary and has offered to use a default label statement in place of testing.

The product, Lilly/Miller Moss Kil Granules, is a residential use herbicide containing zinc sulfate monohydrate (99%) as the active ingredient. Lilly/Miller Moss Kil Granules was placed in batch 2 of the RED. The remaining acute toxicity requirements have been satisfied.

The study was performed by Cosmopolitan Safety Evaluation and the MRID number is 426950-03.

RECOMMENDATION

1. **Dermal Sensitization;** Supplementary

Induction should be performed with a mild to moderately irritating concentration. The concentration chosen in the three subject study failed to induce any positive responses during the induction exposures. PRS considers induction concentrations which produce (positive) dermal irritation much more likely to activate the immune system than concentrations which produce no irritation. Therefore, the data is not deemed adequate to base a decision regarding the dermal sensitization potential of this product.

Furthermore, since PRS does not allow unsubstantiated labeling in place of acute data requirements, the registrants proposal to employ a default label statement is unacceptable. Some form of valid data or information is needed as a basis for this labeling decision. It is recommended that the registrant provide a new dermal sensitization study, cite existing data or reference literature which indicates the sensitization potential of zinc sulfate in order to support the reregistration of this product.

LABELING

See 3/3/94 PRS review of this product for current precautionary labeling recommendations. These recommendations may change following the review of additional submitted/cited acute data.

NOTE TO PM: Due to eye irritation, this product meets the criteria for child-resistant packaging and restricted use classification. The PM should decide if the label contains sufficient alternative labeling language to offset the hazard and the need for restricted use classification.